

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	§	
Clark R. Baker, Jr.	§	Confirmation No.: 1106
	§	
Serial No.: 10/796,584	§	Group Art Unit: 3737
	§	
Filed: March 8, 2004	§	Examiner: Ramirez, John Fernando
	§	
For: Method and Apparatus for Optical	§	Atty. Docket: TYHC:0149/FLE/COH
Detection of Mixed Venous and	§	P0409R
Arterial Blood Pulsation in Tissue	§	

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December 29, 2008	/W. Allen Powell/
Date	W. Allen Powell

REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41

This Reply Brief is being filed in furtherance of the Notice of Appeal mailed on October 22, 2007, and received by the Patent Office on October 24, 2007, and the Appeal Brief filed on February 4, 2008, and in response to the Examiner's Answer mailed on October 30, 2008.

In the Examiner's Answer, the Examiner withdrew the rejection of claims 1-22 under 35 U.S.C. § 112. Examiner's Answer, page 2. Accordingly, the only remaining ground of rejection under review is the Examiner's rejection of claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) as being unpatentable over Diab et al. (U.S. Pub. No. 2003/0036689) in view of Swedlow et al. (U.S. Patent No. 5,662,106). See Examiner's Answer, page 3. Of these, claims 1 and 13 are independent. Appellant respectfully requests the Board overturn the Examiner's rejection of claims 1-4, 6-16, and 18-22 for at least the reasons set forth below.

1. **The Examiner submitted new evidence in the Examiner's Answer which was requested and available before the Final Office Action was mailed.**

The Examiner, in rejecting the present claims, has stated that "it is well known in the art that the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger." Office Action mailed on February 12, 2007, page 3; Final Office Action mailed on August 22, 2007, page 4; Examiner's Answer, page 4. In making this statement, the Examiner essentially took official notice of facts not in the record. *See* M.P.E.P. §2144.03.

In response to the Examiner's taking of official notice, Appellant requested documentary support of the facts which were allegedly "well known" in the art at the time of Appellant's invention. Response to Office Action mailed on February 12, 2007, pages 10-12. In the Final Office Action mailed on August 22, 2007, the Examiner repeated the above-quoted rejection but did not cite any documentary evidence in support of the statement. Final Office Action, page 4. In addition, the Examiner responded to Appellant's arguments by stating as follows:

Applicant alleges on page 10 of the remarks, that the Swedlow reference does not disclose detection of venous pulsation, much less an indication of its presence. The examiner of record respectfully disagrees with applicant's assertions. It is commonly understood in pulse oximetry that the detected physiologic signals in response to both red and infrared light consist of desired signal portions as well as undesired signal portions. The desired signal portions are proportional to one another through the arterial optical density ratio. The resultant is a reference signal that contains only noise portions. Considering the finger for example, the venous blood in the vascular bed will be easily deformed during motion. In addition, the venous blood is a strong absorber of light. Hence, it can represent a significant contributor to the total optical density during motion episodes. During routine patient motions (shivering [*sic*], waving, tapping, etc.), the resulting noise can be quite substantial and can easily overwhelm a conventional ratio

based oximetry system. Having identified the venous blood as a significant contributor to noise during motion. [sic]

Final Office Action, page 2.

In the Appeal Brief, Appellant again noted that the Examiner's rejection relied on official notice for which no documentary evidence had been supplied. Appeal Brief, pages 13-15. In addition, Appellant requested that the Board overturn the Examiner's rejection at least based on the lack of documentary evidence to support facts allegedly "well known" in the art at the time the present application was filed and on which the Examiner's rejection relied. *See id.* In response to this request, the Examiner finally cited evidence in the Examiner's Answer. Examiner's Answer, pages 3 and 4.

Appellant respectfully asserts that this evidence was improperly submitted and should not be considered by the Board. Specifically, the Examiner's submission of new evidence which had been requested before the Appeal Brief is not proper and should have been designated as a new ground of rejection. Regarding new evidence to support official notice, the M.P.E.P states:

Where a newly cited reference is added merely as evidence of the prior statement made by the examiner as to what is "well-known" in the art which was challenged for the first time in the appeal brief, the citation of the reference in the examiner's answer would not ordinarily constitute a new ground of rejection within the meaning of 37 CFR 41.39(a)(2).

M.P.E.P. §1207.03 (emphasis added). As noted above, Appellant first challenged the Examiner's statement as to what was "well known" in the art in the Response to Office Action mailed on February 12, 2007. The Examiner clearly had possession of the cited reference at the time of the Final Office Action, as evidenced by the copying of entire sentences from the reference into the Final Office Action. *See Masimo, Signal Extraction Technology*, pages 4-5.

The Examiner's failure to submit evidence in response to Appellant's request was clearly erroneous. As discussed above, Appellant properly traversed the Examiner's assertion of "well known" facts and requested evidence in support of the Examiner's assertion as to what was "well known" at the time of Appellant's invention. See Response to Office Action mailed on February 12, 2007, pages 10-12. The Examiner then maintained the rejection while failing to provide documentary evidence in the next Office Action as required by 37 CFR 1.104(c)(2). M.P.E.P. § 2144.03(C). In summary, the Examiner's statement was first challenged in a non-final Office Action, not in the Appeal Brief, and therefore the requested evidence should have been submitted in the subsequent Office Action, not in the Examiner's Answer.

2. The evidence submitted by the Examiner in support of facts "well known" in the art at the time Appellant's application was filed is dated after the filing date of the present application.

In addition to the errors set forth above, the evidence submitted by the Examiner in support of the statement as to what was "well known" in the art at the time Appellant's application was filed is dated after the filing date of the present application. Specifically, the reference is dated 2006, whereas the present application was filed on March 8, 2004. Accordingly, the cited reference does not demonstrate what was known in the art at the time of the invention and cannot be considered prior art. For at least these reasons, Appellant respectfully requests that the Board not consider the cited reference in support of the Examiner's official notice of facts outside the record. Because the Examiner improperly relied on the cited reference in the rejection of claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a), Appellant respectfully submits that the Examiner has not set forth a *prima facie* case of obviousness with respect to these claims.

3. **Even if, *arguendo*, the Examiner's assertion of facts "well known" in the art at the time Appellant's application was filed is correct, the Examiner has not set forth a *prima facie* case of obviousness regarding independent claims 1 and 13, or their dependent claims.**

In addition, even assuming, *arguendo*, that the Examiner's statement of what was "well known" in the art at the time of Appellant's invention is correct, which Appellant does not concede, the Examiner has not explained how the asserted facts obviate the deficiencies of the primary and secondary references in the rejection under 35 U.S.C. § 103(a). Specifically, the Examiner rejected claims 1-4, 6-16, and 18-22 as obvious over the Diab reference in view of the Swedlow reference. Although neither reference discusses detecting venous pulsation or indicating the presence of venous pulsation to a caregiver when detected, as recited in independent claims 1 and 13, the Examiner argued that the Diab and Swedlow references teach these limitations because "it is well known in the art that the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger." Office Action mailed on February 12, 2007, page 3; Final Office Action mailed on August 22, 2007, page 4; Examiner's Answer, page 4. As the Examiner explained, this alleged fact shows that patient movement causes deformation of venous blood. See Examiner's Answer, page 6. There is no discussion of venous pulsation in the Examiner's explanation of the relevance of the cited reference. See *id.*

Contrary to the Examiner's assertions, the Diab and Swedlow references also do not discuss venous pulsation. The central dispute between the Examiner and the Appellant seems to be based on the meaning of the term "venous pulsation" as recited in independent claims 1 and 13 and as described in the present application. As discussed in the present application, venous pulsation is a phenomenon in pulse oximetry which may interfere with the calculation of various physiological parameters, such as oxygen saturation or pulse rate. Application, ¶ [0038]. Venous pulsation is generally believed to be caused by venous blood backing up and pooling due to a lack of sufficient valves in the vascular anatomy. *Id.* Venous pulsation is more common in certain areas of the body where there are fewer valves, such as the head or forehead. *Id.* In addition, a patient's

medical condition may increase the likelihood that venous pulsation will occur. *Id.* Typically, caregivers are instructed to secure sensors to patients tightly enough to overcome any venous pulsation, but it is not easy to determine whether any particular sensor has been secured properly. Application, ¶ [0039]. Venous pulsation is a different phenomenon from motion artifact, which may be caused by patient movement, such as shivering, finger tapping, waving, and so forth. Indeed, a patient who is lying perfectly still may experience venous pulsations.

In contrast, the Diab reference discloses a system where the venous saturation is quantified. Specifically, the Diab reference calculates an arterial saturation and a venous saturation. *See* Diab, ¶ [0395]. To measure the venous saturation, Diab uses arterial saturation values, and the venous saturation measurement appears to derive from arterial saturation measurements. *See id.* The Diab reference explains:

In order to obtain the venous saturation, the minimum arterial saturation value, of points that exhibit non-zero value, is selected rather than the maximum arterial saturation value. The saturation can be provided to the display 336.

Id.

Regarding the passages cited by the Examiner in the Final Office Action, the Diab reference discloses that a plethysmographic wave contains primary and secondary portions. *See* Diab, ¶ [0019]. The secondary portion is noise and may include several parameters, including patient movement, venous blood contribution to attenuation of energy as it passes through the body, and respiration. *See id.* A parameter “n” utilized in algorithms disclosed in the Diab reference represents noise, including “information on the venous blood, as well as motion artifacts and other noise.” Diab, ¶ [0368] (emphasis added). The sources of noise in the secondary portion of the plethysmographic wave are not sorted or specifically identified. Diab does not disclose a method or means for detecting venous pulsation but rather discloses that a portion of the plethysmographic

wave may include a hodgepodge of various noise signals. That is, the secondary portion of the plethysmographic wave may or may not contain noise due to venous pulsation.

Regarding the phase difference measurement recited in claims 1 and 13, the Diab reference discusses a phase difference measurement between red and IR signals; however, this measurement is not obtained to form a comparison with a threshold to detect the presence of venous pulsation. See Diab, ¶¶ [0389]-[0393]. Rather, according to the Diab reference, if the phase difference between a red and IR point is low enough, the points are used to calculate a saturation value. See Diab, ¶¶ [0393]-[0394]. That is, the Diab reference discloses calculation of arterial and venous saturation. See Diab, ¶ [0395]. Appellant finds no discussion in the Diab reference regarding detecting the presence or absence of a venous pulsation.

Furthermore, the Swedlow reference does not cure the deficiencies of the Diab reference. The Swedlow reference discloses modification of an alarm condition when motion is detected. See Swedlow, Abstract. Nothing in the Swedlow reference discloses detection of venous pulsation, much less an indication of its presence. Rather, the Swedlow reference merely discloses a pulse oximeter that detects motion artifacts. See Swedlow, col. 1, lines 10-13; col. 2, lines 52-53; col. 5, line 64 – col. 6, line 14. Specifically, the Swedlow reference relates to detection of a motion artifact, “such as by the detector moving away from the skin temporarily.” Swedlow, col. 2, lines 14-15. Again, a motion artifact is not equivalent to venous pulsation as recited in the present claims. Accordingly, detection of motion artifacts does not teach detection of venous pulsations.

Despite the complete lack of any discussion regarding detecting the presence or absence of venous pulsation in either the Diab or Swedlow reference, the Examiner continued to assert that claims 1 and 13 are obvious in view of these references. See Examiner’s Answer, pages 3-5. Specifically, the Examiner relied on the allegedly “well known fact” that “the primary cause of noise in transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger.”

Examiner's Answer, page 6. The Examiner went on to state that venous blood is a significant contributor to signal noise during motion. *Id.* Even if this was a well known fact at the time of Appellant's invention, this information does not obviate the deficiencies of the Diab and Swedlow references. Specifically, venous blood is not the same as venous pulsations. Even the reference the Examiner relied upon in support of the assertion of "well known facts" merely discloses that deformation of venous blood may contribute to noise during motion episodes. Masimo, Signal Extraction Technology, pages 4-5. Again, motion artifact and venous pulsation are not the same phenomenon, and detection of one does not constitute detection of the other.

Additionally, in an interview between Appellant's attorney and the Examiner on December 22, 2008, Appellant's attorney pointed out that the evidence submitted by the Examiner in support of the alleged "well known facts" relied upon in the rejection under 35 U.S.C. § 103(a) did not demonstrate that motion artifact and venous pulsation are equivalent or interchangeable phenomena. *See* Interview Summary filed herewith. In response, the Examiner stated that the argument set forth on page 6 of the Examiner's Answer did not mention venous pulsation. *See id.* Appellant's attorney reminded the Examiner that the present claims are directed to detection of venous pulsations and therefore the Examiner's statement was confusing. *See id.* Indeed, in the Final Office Action, the Examiner disagreed with Appellant's assertion that the Swedlow reference does not disclose detection of venous pulsation in view of the "well known fact" that venous blood is a significant contributor to noise due to motion (i.e., motion artifact). Final Office Action, page 2.

In summary, neither the Diab nor Swedlow reference discloses "detecting the presence or absence of venous pulsation" as recited in independent claims 1 and 13. Nor does either reference disclose "indicating the presence of venous pulsation to a caregiver if venous pulsation is present." Additionally, the "well known facts" asserted by the Examiner fail to obviate the deficiencies of the cited references. Even if it was well known at the time of Appellant's invention that "the primary cause of noise in

transmissive pulse oximetry measurements is motion artifact caused by the movement of venous blood in the finger,” which Appellant does not concede, this alleged fact would not render the present claims obvious over references relating to motion artifact. That is, the presence of motion artifact (i.e., noise due to patient movement) does not indicate the presence of venous pulsation (i.e., a phenomenon which can be present without any patient movement), or vice versa. In view of the above arguments, Appellant respectfully requests the Board overturn the Examiner’s rejection of claims 1-4, 6-16, and 18-22 under 35 U.S.C. § 103(a) and indicate allowance of all pending claims.

If the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: December 29, 2008

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